IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION

Case No. 1:15-cv-07488-CM (RWL)

FOREST'S OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* NO. 6: PRECLUDE "LITIGATION RISK" OR "RISK AVERSION" OR PURPORTED "EARLY ENTRY" AS PROCOMPETITIVE JUSTIFICATIONS

WHITE & CASE LLP

Counsel for Defendants Actavis plc, Forest Laboratories, LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd.

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DPPs' motion *in limine* number 6 seeks to preclude Forest from presenting evidence on two loosely related topics — "risk aversion" and early entry. The motion should be denied as to both issues.

ARGUMENT

I. Evidence of Both Business Uncertainty During Litigation and the Separate Concept of Risk Aversion Are Relevant and Admissible Considerations

DPPs assert that Forest should be precluded from arguing that it is "risk averse," and that risk aversion should be read broadly to include a desire for "business certainty" that might otherwise be prevented by the litigation process. ECF No. 744, Mem. in Supp. of Pls.' Mot. *In Limine* No. 6: Preclude "Litigation Risk" or "Risk Aversion" or Purported "Early Entry" as Procompetitive Justifications ("DPPs' MIL 6") at 1, 3. But DPPs' motion misconstrues Forest's arguments and is premised on a misunderstanding of the structure of the rule of reason.

DPPs improperly seek to preclude Forest from offering its business justifications for the settlement by conflating business certainty with risk aversion. DPPs' MIL 6 at 3 ("The Court should likewise block any attempt by Defendants to 'backdoor' a risk aversion defense under the guise of the avoidance of 'business (un)certainty.'"). But as other courts have held, Forest's business reasons for settling, including a general preference for settlement, the certainty settlement provides, and the elimination of costly distractions to management (among other reasons), are relevant and cognizable explanations for the alleged payment under *Actavis*. *See, e.g.*, *In re Lidoderm Antitrust Litig.*, No. 3:14-md-02521, 2018 WL 7814761, at *7 (N.D. Cal. Feb. 7, 2018) (holding evidence of "certainty and fewer distractions" may be relevant under step one of the rule of reason as explanations for the alleged payment).

DPPs also mischaracterize Forest's argument as seeking to justify the alleged payment to Mylan through what DPPs calls "risk aversion"; in reality, Forest intends to offer evidence of risk

aversion not as a justification, but because risk aversion is relevant to the issue of causation. Such argument is plainly proper under *Actavis*.

A. *Actavis* Does Not Preclude Forest from Offering Evidence of Business Justifications, Including Avoiding the Cost of Business Uncertainty

DPPs' claim that *Actavis* forecloses evidence of "business uncertainty" is simply incorrect. DPPs' MIL 6 at 3-6. *Actavis*' concern with large and unexplained payments stems from a concern that the only explanation for such a payment may be that it was made to protect a weak patent. *See FTC v. Actavis, Inc.*, 570 U.S. 136, 157-58 (2013) (expressing view that size of payment, relative to explanations, can be used to glean "that the patentee has serious doubts about the patent's survival"). Because business reasons for a payment may be independent of any consideration of the relative patent merits, *Actavis* did not foreclose defendants from putting forth evidence that an alleged payment is "explained" by business reasons. *Id.* at 156.

In fact, *Actavis* calls for an open-ended inquiry under the rule of reason into explanations for the payment, other than patent weakness. *Id.* (allowing defendant to show a payment is explained by "traditional settlement considerations" including "avoided litigation costs," "fair value for services," or "other justifications"); *see also Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877, 885-86 (2007) ("Under [the rule of reason], the factfinder weighs all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition. Appropriate factors to take into account include 'specific information about the relevant business' . . . .") (citation omitted). Indeed, the Supreme Court in *Actavis* rejected the FTC's "quick look" test in favor of the broad examination of context embodied in the rule of reason. *Actavis*, 570 U.S. at 158-59.

The avoidance of business uncertainty is a valid business explanation for a settlement. Indeed, business uncertainty is a "cost" of litigation as surely as paying lawyers or experts or court

reporters, and certainly part of the context of a patent settlement agreement. In fact, it would make little sense to say that a patent holder can pay to avoid litigation expenses — which *Actavis* specifically allows and DPPs do not contest — but not to avoid the cost of business uncertainty. *Id.* at 156 ("Where a reverse payment reflects traditional settlement considerations, such as avoided litigation costs . . . there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement."). So long as litigation remains pending, a business must operate under a cloud of uncertainty and cannot properly plan for the future — particularly if its businesspeople are diverted into the litigation process rather than being able to devote their time and attention to business planning and business operations. *See, e.g.*, *Ironworkers Dist. Council v. Andreotti*, C.A.-9714-VCG, 2015 Del. Ch. LEXIS 135, at *80 (Del. Ch. Ct. May 8, 2015) (corporation could rightly consider the time, expense, and business impact of litigation, including the "significant distraction and impairment of morale for directors, officers, and employees of the Company"); Michaela Keet, Heather Heavin, & Shawna Sparrow, *Indirect and Invisible Organizational Costs: Making Informed Decisions about Litigation and Settlement*, 20 Cardozo J. Conflict Resol. 49, 51 (2018) ("a cost-benefit analysis of whether to litigate or settle must account for indirect organizational costs as well as direct legal expenses"). The cost of this uncertainty, and of diverting businesspeople in this way, is *not* a "risk" of the litigation outcome — a business involved in litigation suffers these costs whether it ultimately wins or loses — but a cost that flows from being in litigation. Thus, DPPs are incorrect to characterize as "risk aversion" the desire to avoid the cloud of uncertainty and the costs to the business of being in litigation; if anything, this desire is better characterized as "litigation aversion," the desire simply not to have to litigate.

Indeed, a general preference for settlement and the benefits of settling, including certainty and freedom from unnecessary distractions, are quintessential reasons for settling any case (patent litigation or otherwise), and squarely fall into "traditional settlement considerations" specifically recognized by *Actavis*. 570 U.S. at 156. Those benefits are unrelated to the strength of the patent.

Settlement can be particularly beneficial because the business costs associated with litigations (in terms of executive time and distraction) can be substantial. Moreover, business certainty associated with settlement of any litigation allows companies to more efficiently budget and allocate resources. Ex. 1, Expert Report of Lona Fowdur, Ph.D. at ¶ 75 ("The settlement likely also benefited Forest by reducing its uncertainty about the timing of entry for generic IR . . . . [T]he settlement reasonably would be expected to allow Forest to allocate its resources more efficiently and profitably."); *see also* Saul Morgenstern & Adam Pergament, *Commentary: Applying the Rule of Reason in the Post*-Actavis *World*, 2018 Colum. Bus. L. Rev. 45, 56 ("The settlement of bona fide patent litigation is both lawful and procompetitive. Among other benefits, settlements provide certainty . . . . That certainty is important to the generic, it is important for the brand, and it is important to the patients and payers. It saves the parties money, business time, and the distraction of litigation."). As such, Forest's business reasons for settling are valid explanations for the alleged payment. *See* Order at 2, *Apotex, Inc. v. Cephalon, Inc.*, No. 2:06-cv-02768 (E.D. Pa. July 5, 2017), ECF No. 1256 (denying motion to preclude "business reasons" for settlement); *see also* Bret Dickey, Jonathan Orszag & Laura Tyson, *An Economic Assessment of Patent Settlements in the Pharmaceutical Industry*, 19 Ann. Health L. 367, 375 (2010) ("Patent settlements provide clear benefits by reducing litigation costs. In general, the cost of litigating includes (1) direct litigation costs, (2) indirect costs, ***such as requiring the attention of company***

executives, distracting them from the operation of the business, and (3) costs due to the uncertainty of litigation outcomes.") (emphasis added).

The cases DPPs cite (DPPs' MIL 6 at 2) do not contradict this basic principle, nor do they take such a sweeping view of *Actavis* as DPPs take here. The *Lidoderm* decision cited by DPPs (*id.*) is particularly instructive. In *Lidoderm*, the plaintiffs moved to preclude the defendants from arguing that "certainty and fewer distractions" was a justification for the patent settlement agreement. 2018 WL 7814761, at *7. Noting the difference between plaintiffs' burden at step one of "large and unexplained" and step two of procompetitive benefits, the court held that issues of certainty and fewer distractions "may . . . be relevant to whether the reverse payments were 'large and unexplained' . . . ." *Id.* This delineation of burdens is consistent with *Actavis*, which addressed whether that a payment was "large" and "unexplained" under step one of the rule of reason separately from the procompetitive justifications assessed under step two of the rule of reason. *See Actavis*, 570 U.S. at 158-59 (rejecting invitation to adopt "quick look" test which would "shift[] to 'a defendant the burden to show empirical evidence of procompetitive effects'" and instead placing burden on plaintiff to show "anticompetitive effects" through a "large and unjustified" payment).

B. DPPs Admit that Evidence of Risk Aversion Is Relevant to the Issue of Causation

Nor should the Court preclude evidence of *actual* "risk aversion," as DPPs suggest. DPPs' MIL 6 at 1-3. Risk aversion, when accurately defined, is relevant to the issue of causation. Risk aversion is not, as DPPs claim, a concern by Forest about the strength of the patent. DPPs' MIL 6 at 1-2 (discussing risk aversion as an attempt to "avoid the risk of patent invalidation or a finding of noninfringement") (emphasis omitted). Instead, risk aversion is the risk associated with ***earlier than appropriate*** generic entry given the objective strength of the patent. Indeed, DPPs admit that this sort of evidence of risk aversion is relevant to causation. DPPs' MIL 6 at 3 ("In *Wellbutrin*

XL, the focus was not on justifications for the reverse payment, but on whether the reverse payment was itself sufficient evidence of patent invalidity to overcome a *causation* defense.") (emphasis added).

In order to succeed at trial, DPPs must show that the Forest-Mylan settlement caused delayed generic entry. *See In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 199-201 (S.D.N.Y. 2018) ("The viability of Plaintiffs' Section 1 claim 'will depend on the presence of evidence suggesting that the settlement agreements did, in fact, delay generic entry' . . . ."). And as *Wellbutrin* held, risk aversion is relevant to causation because it "serves as an effective rebuttal to the [plaintiffs'] claim that the size of the reverse payment is a 'surrogate' for the weakness of the [] patent." *In re Wellbutrin XL Antitrust Litig.*, 868 F.3d 132, 168-69 (3d Cir. 2017). In other words, even if DPPs prove that Forest made a large and unexplained payment, causation cannot be presumed because a risk averse patentee may pay to obtain the certain outcome associated with settlement, even if the patent is objectively strong. *Id.*

Nor was *Wellbutrin* limited, as DPPs claim, to the issue of whether a "blocking patent" was invalid or non-infringed. DPPs' MIL 6 at 3. Instead, in discussing the size of the payment generally, the court noted that they were "persuaded" as to "why risk aversion makes it difficult to use the size of a settlement as a proxy for the brand-name's likelihood of success in the litigation." 868 F.3d at 168. Thus, risk aversion is a relevant and "effective rebuttal" to DPPs' arguments on causation. *Id.*

II. Permitting Early Entry of Generic Namenda IR is a Procompetitive Benefit of the Namenda Patent Settlement Agreements

DPPs' final argument — that Forest should be precluded from "asserting that Mylan's July 11, 2015 entry was 'early' and therefore a procompetitive justification for the reverse payment" — also should also be rejected. DPPs' MIL 6 at § B. Nothing in *Actavis* precludes Forest from

arguing that its settlement with Mylan permitted Mylan to enter earlier than it otherwise would have been able to. In fact, *Actavis* recognized that early entry under a settlement agreement would be a procompetitive benefit. *See* 570 U.S. at 154 ("We concede that settlement on terms permitting the patent challenger to enter the market before the patent expires would also bring about competition, again to the consumer's benefit."); *see also In re Namenda Direct Purchaser Antitrust Litig.*, No. 15-cv-07488, 2017 U.S. Dist. LEXIS 83446, at *60 (S.D.N.Y. May, 23, 2017) (quoting same passage of *Actavis*).

DPPs fail to mention that before the factfinder gets to procompetitive justifications under the rule of reason, it is DPPs' burden, as part of step one of the rule of reason, to prove anticompetitive effects through a large and unexplained payment that "did, in fact, delay generic entry." *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc*, No. 15-cv-07488, 2016 U.S. Dist. LEXIS 128349, at *50-51 (S.D.N.Y. Sept. 13, 2016). DPPs attempt to short-circuit their burden under the rule of reason by *assuming* the presence of a reverse payment that delayed generic entry. But only after DPPs have satisfied their burden under step one does the burden shift to Forest to show procompetitive justifications in step two. *See In re Namenda*, 331 F. Supp. 3d at 197-98.

While DPPs are entitled to present evidence that the Forest-Mylan settlement agreement contained a reverse payment that caused delay, Forest is not precluded from arguing the opposite. Indeed, Forest intends to present evidence that the settlement provided Mylan with earlier entry than it would have been able to secure through patent litigation. ECF No. 699-2, Defs.' Contentions at 7-9. Ultimately, whether the settlement in fact caused delay is the ultimate issue for the jury to decide. Forest cannot be precluded from offering evidence that its settlement accelerated, not delayed, generic entry. *C.f.* Fed. R. Evid. 702 advisory committee's notes ("When

facts are in dispute, experts sometimes reach different conclusions based on competing versions of the facts."). In fact, this Court has already repeatedly recognized the procompetitive nature of Forest's early-entry licenses to the generic challengers. *See Sergeants Benevolent Ass'n*, 2016 U.S. Dist. LEXIS 128349, at *50 ("The settlement terms permitted generic entry three months *before* Forest's patent exclusivity period expired, which, in effect, expedited the entry of generic competition into the market for memantine therapy.") (emphasis in original); *In re Namenda*, 2017 U.S. Dist. LEXIS 83446, at *53 ("The problem with Plaintiffs' argument is that the settlement agreements permitted the Generic Competitors to enter the market *earlier* than they could have if Defendants had prevailed in the patent infringement litigation — a *generally procompetitive* result.") (emphasis in original).

Nor is Forest attempting to reanimate the "scope of the patent" standard as DPPs contend. DPPs' MIL 6 at 7. Under the scope of the patent jurisprudence, a patent settlement was *immunized* from scrutiny so long as the settlement permitted the alleged infringer to enter during the patent period. *Actavis*, 570 U.S. at 146-48. Forest does not intend to argue to the jury that the settlement is immunized from scrutiny because it permitted Mylan to enter prior to patent expiry. Nevertheless, the fact that the settlement permitted entry prior to patent expiry is one factor the jury should consider when evaluating whether the settlement, as a whole, was procompetitive or anticompetitive.

Further, DPPs are incorrect that procompetitive justifications must be limited to justifying the "payment." DPPs' MIL 6 at 6. Courts applying *Actavis* have routinely rejected such a narrow interpretation, instead viewing the challenged agreements as a whole. *See, e.g.*, *In re Loestrin 24 Fe Antitrust Litig,* 261 F. Supp. 3d 307, 330-31 (D.R.I. 2017) (viewing agreement "as a whole . . . to determine its alleged effect on competition"); *In re Wellbutrin XL Antitrust Litig.*, 133 F. Supp.

3d 734, 754 (E.D. Pa. 2015) ("The Wellbutrin settlement was negotiated as a whole, agreed to as a whole, and went into effect as a whole, so failing to evaluate the agreement as a whole would overlook context essential to determining any possible anticompetitive effects."), *aff'd* 868 F.3d 132 (3d Cir. 2017). As such, Courts reject similar arguments to those made by DPPs here to exclude evidence of early entry. *See, e.g.*, *In re Solodyn (Minocycline) Antitrust Litig.*, No. 14-md-02503, 2018 U.S. Dist. LEXIS 18979, at *24-27 (D. Mass. Feb. 6, 2018) (denying motion to exclude expert's testimony that "early entry . . . justified" settlement agreement); *Lidoderm*, 2018 WL 7814761, at *7-8 (holding "'early' entry" was a permissible procompetitive justification). This Court should similarly reject DPPs' motion seeking to exclude evidence that the settlement agreement allowed for early generic entry.

CONCLUSION

Forest respectfully requests that this Court deny Plaintiffs' Motion *In Limine* No. 6.

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Respectfully submitted,

WHITE & CASE LLP

By: */s/ Martin M. Toto*

Martin M. Toto
Heather K. McDevitt
John H. Chung
Michael E. Hamburger
William H. Bave, III
Kristen O'Shaughnessy
Kevin C. Adam
WHITE & CASE LLP
1221 Avenue of the Americas
New York, New York 10020
Telephone: (212) 819-8200

J. Mark Gidley
Christopher M. Curran
Eric Grannon
WHITE & CASE LLP
701 Thirteenth Street, NW
Washington, DC 20005

Beth Wilkinson
Rakesh Kilaru
Kieran Gostin
WILKINSON WALSH + ESKOVITZ
2001 M Street NW, 10th Floor
Washington, D.C. 20036
Telephone: (202) 847-4000

Counsel for Defendants Actavis plc, Forest Laboratories, LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd.

Telephone: (202) 626-3600

Heather M. Burke
Eric E. Lancaster
WHITE & CASE LLP
3000 El Camino Real
2 Palo Alto Square, Ste. 900
Palo Alto, CA 94306
Telephone: (650) 213-0300

Counsel for Defendants Actavis plc, Forest Laboratories, LLC, Forest Laboratories, Inc., and Forest Laboratories Holdings Ltd.